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CYTYC CORPORATION
Darry Pattinson, Sr. IP Paralegal
250 CAMPUS DRIVE
MARLBOROUGH, MA 01752

EXAMINER	
RASHID, DAVID	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,978	ROEHRIG ET AL.	
	Examiner	Art Unit	
	DAVID P. RASHID	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,7,9,10,22,23,25-29 and 31-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,7,9,10,22,23,25-29 and 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Table of Contents

Amendments & Claim Status

[1] This office action is responsive to the Reponse received on September 17, 2008. Claims 1-2, 4-5, 7, 9-10, 22-23, 25-29, and 31-33 remain pending.

Response to Arguments

[2] Remarks filed September 17, 2008 with respect to claims 1-2, 4-5, 7, 9-10, 22-23, 25-29, and 31-33 have been respectfully and fully considered, and found persuasive.

Summary of Remarks regarding Claims 1-2 and 4-5§ 103 Rejections

> The combination of Giger and Nokita fail to teach or describe such a system. The Giger system merely describes a method of processing a single image, whereby background correction is performed on dense portions of the image, and the image is 'normalized' by returning it to its original gray values. The Examiner appears to state that the 'normalization' of Giger is analogous to the claimed language of 'processing the processed x-rag medical image according to

> predetermined *values for said at least one operating parameter or physical characteristic* to generate a standard-form version of said x-ray medical image characterizing the x-ray medical image of the object that would have been obtained by the x-ray device using said predetermined values therefore..." However, Applicant would submit that such a characterization does not give patentable weight to the claimed term 'predetermined values for said at least one operating parameter or physical characteristic', or the fact that the 'standard-form' is generated to characterize the x-ray medical image as if it 'would have been obtained by the x-ray device *said predetermined values therefore...* The claims highlight the fact that part of the invention lies in the recognition that a certain values (x-ray energies, breast thickness, etc.) are preferred in view of the energy dependence of breast x-ray attenuation, and the method that is used to ensure that images are processed according to the predetermined values associated with the preferred view.
>
> Although the Examiner appears to rely column 5, lines 55-60 as teaching that the initial image 'processing' may include 'subtraction process.., in terms of relative x-ray exposure...', it is noted that the normalization process of Giger describes *only* a modification of gray levels to reach the 'normalized' (original) gray value levels. There is no teaching or suggestion in Giger of"...processing the processed x-ray medical image according to predetermined values for said at least one operating parameter or physical characteristic to generate a standard-form version of said x-ray medical image characterizing the x-ray medical image of the object that would have been obtained by the x-ray device using said predetermined values therefore..." as recited in the claims.

Applicant's Remarks at 14-15, September 17, 2008.

However, restricting the "processing the processed x-ray medical image" method-step to read only "certain values (x-ray energies, breast thickness, etc) [to be] preferred in view of the energy dependence" with respect to the "predetermined values" is unpersuasive.

The Examiner interprets "predetermined values" to consist those needed to construct the "subtracted" processed x-ray medical image back to the original digital image item 800, fig. 8 (e.g., the gray level values from relative x-ray exposure). Predetermined values are needed to revert the subtracted image from item 803 back to its original state using the normalization process item 804. *See* fig. 3 (the digital medical image) and fig. 9 (the standard-form version).

For example, matching gray-values during the normalization process itself is sufficient to read on said method-step above. If the "predetermined values" consist of the "average gray level" of the original image (the operating parameter or physical characteristic being that the image is constructed of gray levels), then the image is being processed according to average gray level values for at least those gray levels in the image to generate the standard-form "dense-portion correction" version (fig. 9) using the normalization process.

The Examiner suggests further limiting what is meant by "predetermined values" and "at least one operating parameter or physical characteristic" such that a broad gray-level value and

relative x-ray exposure interpretation cannot be read anymore (e.g., putting in the claim "certain values (x-ray energies, breast thickness, etc) [to be] preferred in view of the energy dependence").

> The Examiner admits on page 5 of the office action that "Giger does not disclose generating a standard-form version of said x-ray medical image", but states that Nokita does. However, Applicant's can find *no teaching or suggestion* in Nokita for generating a standard- form medical image. Nokita focuses solely on the movement of an anti-scatter grid. The Examiner relies on the language of Nokita, which uses the language 'standard imaging conditions'. However, even if there were 'imaging' conditions that were 'standard', such a teaching does not describe or suggest an image that has a 'standard=form'.

Remarks at 15-16.

Applicant's argument is found persuasive arguing the § 103 combination between *Giger* and *Nokita*. However, *Giger* does disclose a standard-form version if "standard-form" is interpreted as (i) a version brought back to its original state; and (ii) that original state having "standard" characteristics. The original image version of *Giger* (e.g., fig. 3; fig. 8, item 800) contains standard characteristics because it was produced by "relative x-ray exposure" and standard settings to produce a standard digital image. After normalization it has been brought back to its original state (e.g., fig. 3 and fig. 9 after fat removal from subtraction process).

Summary of Remarks regarding Claims 7, 25, and 28-29 § 103 Rejections

> It is first noted that the John reference, which describes attenuation of different materials, fails to overcome the inadequacies described above with regard to the combination of Giger and Nokita. In addition, the John reference fails to state that the x-ray image of the reference material *is formed at the same time as the mammogram and under substantially the same conditions*... For at least this reason, it is respectfully submitted that claims 7, 25 and 29 are patentably distinct over the combination of references and it is requested that the rejection be withdrawn.

Remarks at 18.

However, though stated where the *John* reference fails, it is unclear how the John reference fails to overcome the inadequacies described. "[T]he x-ray image of the reference material is formed at the same time as the mammogram and under substantially the same conditions" is highly subjective as there is no definite time values to interpret what is meant by "substantially" (e.g., performed in the same room) and "same time" (e.g., within 2 minutes). The

Examiner would be allowed to interpret this as reasonably broad as possible, which is supported by the *John* reference.

Summary of Remarks regarding Claims 19-10, 26-27, 31-32 § 103 Rejections

> However, even if Santurtun mentions a typically used kVp and mA, there is no mention or suggestion in Santurtun of a *standard-form image,* which has been generated by processing using predetermined values. Thus, Santurtun fails to overcome the inadequacies described above in the combination of Giger and Nokita.

Remarks at 19.

Applicant's argument is found persuasive arguing the § 103 combination between *Giger* and *Nokita*. See above arguments with respect to "standard-form image" with respect to *Giger*.

Summary of Remarks regarding Claims 22-23 and 33 § 103 Rejections

> Claim 22 recites the steps of : "processing a plurality of digital or digitized mammograms formed by different x-ray mammography systems to remove effects of each mammography system and fat content in the breast being imaged, thereby forming first processed images *converting each first processed image into a standard-form x-ray mammogram having a first standard x-ray voltage parameter and a first standard exposure parameter ...* " As described above, while Giger may process a digitized mammogram to remove effects using a subtraction technique described at column 5 'in terms of gray levels or x-ray exposures', the Examiner has maintained that the *converting* of this image is analogous to the step of normalization in Giger. There is no mention or suggestion in Giger that the normalization is performed based *on first original x-ray voltage parameter and first original exposure parameter* as claimed. Rather, Giger mentions only that normalization 'match(es) the average gray level of the original image).

Remarks at 20-21.

However, gray value levels from the standard form image from fig. 8, item 804 are interpreted to be both a "first standard x-ray voltage parameter" and "first standard exposure parameter" (as the original image itself item 800 contains gray value levels that are also indicative of x-ray voltage values and standard exposure values, and thus the gray value levels also being "parameters" with respect to them). It is suggested to further detail what are both a "first standard x-ray voltage parameter" and "first standard exposure parameter".

Claim Rejections - 35 USC § 101

[3] 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Judicial Exception – Abstract Idea

Claims 1-2, 4-5, 7, 9-10, 22-23, 25-29, and **31-33** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

A judicial exception claim is non-statutory for solely embodying an abstract idea, natural phenomenon, or law of nature. *See* M.P.E.P. § 2106(IV)(C)(2). However, a practical application of a judicial exception claim is a § 101 statutory claim "when it:

(A) 'transforms' an article or physical object to a different state or thing [(*i.e.*, a physical transformation, see below)]; or

(B) otherwise produces a useful, concrete and tangible result, based on the factors discussed below. . . ." *Id.*

§ 101 statutory transformations of intangible articles or physical objects must be physical transformations (*i.e.*, a physical component to the transformation must be involved). [1]

It is suggested to add physical elements (e.g., memory, CPU) within all method-claims such that there exists either (A) a physical transformation and/or (B) tangibility. "[S]toring results. . ." does not positively recite any actual physical element (e.g., a signal can be "stored" just for existing in itself).

In Re Bilski – "Tied To" Criteria

[4] In addition with respect to **claims 1-2, 4-5, 7, 9-10, 22-23, 25-29,** and **31-33**, while the claims recite a series of steps or acts to be performed, a statutory "process" under 35 U.S.C. 101

[1] *See* M.P.E.P. § 2106(IV)(C)(2) (requiring the element "provides a transformation or reduction of an article to a different state of thing", a "practical application by physical transformation") *and* Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, Official Gazette notice, 22 November 2005, Annex (II)(B)(iii); (III).

must (1) be tied to another statutory category (such as a particular apparatus), or (2) transform underlying subject matter (such as an article or material) to a different state or thing.[2]

While the instant claims recite a series of steps or acts to be performed, the claims neither transform underlying subject matter not positively tie to another statutory category that accomplishes the claimed method steps, and therefore do not qualify as a statutory process.

In addition to adding physical elements to the method-claims, it is suggested to sufficiently tie the main concept of the invention to those physical elements.

Claim Rejections - 35 USC § 112

[5] The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-10 and **23** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) Claims 9-10 depend from a cancelled claim - suggest changing to "method of claim 1 ~~8~~ wherein..."

(ii) Claim 23 is an incomplete sentence - suggest adding in elements from claim 4.

Claim Rejections - 35 U.S.C. § 102

[6] The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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[2] *See* Clarification of "Processes" under 35 U.S.C. 101, Deputy Commissioner for Patent Examining Policy, John J. Love, May 15, 2008; *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/section_101_05_15_2008.pdf *and In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008).

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Giger et al.

[7] **Claims 1-2** and **4-5** are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,657,362 (issued Aug. 12, 1997, hereinafter "Giger et al.").

Regarding **claim 1**, *Giger et al.* discloses a method for computer aided detection of medical abnormalities (the highlights are abnormalities in fig. 6) in x-ray medical images (fig. 3; fig. 8, item 800) comprising the steps of:

processing (fig. 8, item 803) a digital or digitized x-ray medical image (fig. 3; fig. 8, item 800) of an object ("breast" at 1:62-65) to remove distinguishing effects ("[t]his subtraction process can be performed. . .in terms of relative x-ray exposure (by use of the characteristic curve in the imaging system)" at 5:57-65) of at least operating parameter or physical characteristics ("relative x-ray exposure" at 5:57-65) of an x-ray device (fig. 27, item 2700) used to form said x-ray medical image (*e.g.*, fig. 3) and the effects of fat content ("pixels below the threshold (i.e., fatty) are not included in determining the fit (step 802). The 2-D fit is then subtracted from the dense regions (step 803)" at 6:23-26) in the object being imaged, thereby forming a processed x-ray medical image (the image after item 803 in fig. 8 is a "subtracted" processed x-ray medical image);

processing (fig. 8, item 804; normalization) the processed x-ray medical image according to predetermined values (the predetermined values needed to construct the "subtracted" processed x-ray medical image back to the original digital image item 800, fig. 8; e.g., the gray level values from relative x-ray exposure) for said at least one operating parameter or physical characteristic ("relative x-ray exposure" at 5:57-65; "gray level") to generate a standard-form version ("dense-portion correction" at 6:40-41; fig. 9; the standard-form version being its original state before removal of distinguishing effects as seen between fig. 3 and fig. 9) of said x-ray medical image ("[t]he resulting image is normalized to match the average gray level of the original image" at 6:27-30) characterizing the x-ray medical image of the object that would have

been obtained by the x-ray device using said predetermined values therefor (normalizing the image would return it to its original state which is now a "dense-portion correction" version); and

processing said standard form version (the image after item 804 in fig. 8 is now a "dense-portion correction" standard form version) of said x-ray medical image (fig. 3; fig. 8, item 800) with a computer aided detection algorithm (fig. 10b; "the incorporation of the dense-portion correction into the mass detection scheme at the preprocessing image-enhancement stage and at the feature extraction stage are shown in FIGS. 10A and 10B" at 6:40-44) that has been optimized with a plurality of x-ray medical images (fig. 10b, item 1005) that have been similarly processed into standard form versions (it is implicit if not already inherent that for a neural network to be trained, similarly processed images are used) thereof using the same predetermined values (the predetermined values needed to construct the original digital image item 800, fig. 8) for said at least one operating parameter or physical characteristic ("relative x-ray exposure" at 5:57-65); and

storing results (fig. 23; fig. 27, item 2706) of the processing of said standard form version (the image after item 804 in fig. 8 is now as standard form version) of said x-ray medical image (the image after item 803 in fig. 8 is a processed x-ray medical image) with the optimized computer aided detection algorithm (see above).

Regarding **claim 2**, *Giger et al.* discloses wherein the x-ray medical image is a mammogram (fig. 3; 2:10-12).

Regarding **claim 4**, *Giger et al.* discloses wherein at least one operating parameter or physical characteristic ("relative x-ray exposure" at 5:57-65) of the x-ray device is selected from the group consisting of x-ray energy; exposure ("relative x-ray exposure" at 5:57-65); and distance between compression plates.

Regarding **claim 5**, *Giger et al.* discloses wherein the processing removes distinguishing effects of the following physical characteristics: anode material; source to image distance; anti-scatter grid geometry; film characteristics; and screen-film system (the subtraction step fig. 8, item 803 removes these effects).

Claim Rejections - 35 U.S.C. § 103

[8] The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Giger et al. in view of Johns et al.

[9] **Claims 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination between *Giger et al.* in view of X-ray characterization of normal and neoplastic breast tissues, Phys. Med. Biol., 1987, Vol. 32, No. 6, 675-695 (*hereinafter* "Johns et al.").

Regarding **claim 7**, while *Giger et al.* discloses wherein an x-ray image of a reference material (fig. 1, element 102; "fat pixels" at 5:49-65) is formed at the same time as the mammogram ("original image" at 5:49-65) and under substantially the same conditions, the method further comprising the step of identifying fat content in the mammogram by comparing exposure values in the mammogram with exposure values on the x-ray image of the reference material (fig.6A-6D; 5:57-57), *Giger et al.* does not teach wherein the reference material has known-x-ray attenuation characteristics representative of different percentages of fat content in the breast.

Johns et al. discloses an x-ray characterization of normal and neoplastic breast tissue (Abstract, pg 675) wherein reference material has known-x-ray attenuation characteristics representative of different percentages of fat content in the breast (Section I. Introduction, page 676, third paragraph. Since the measuring was done on multiple patients and the fact each breast contains a distinct percentage of fat content, the x-ray attenuation characteristics are representative of different percentages of fat content in the breast.).

It would have been obvious to one of ordinary skill in the art at the time the invention was made for the method of *Giger et al.* to include the reference material having known x-ray attenuation characteristics representative of different percentages of fat content in the breast as taught by *Johns et al.* for "...the detection of infiltrating duct carcinomas in a fibrous breast.", Johns, Section I. Introduction, page 676, fifth paragraph in the case of single-energy imaging,

and for "…imaging carcinomas with suppression of 'clutter' due to fat/fibrous contrast.", *Johns et al.*, Section I. Introduction, page 676, fifth paragraph in the case of dual-energy.

Giger et al. in view of Manueco Santurtun et al.

[10] **Claims 9-10** and **26-27** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Giger et al.* in view of U.S. Patent No. 4,596,029 (issued Jun. 17, 1986, *hereinafter* "Manueco Santurtun et al.").

Regarding **claim 9**, while *Giger et al.* discloses the method of claim 1, *Giger et al.* does not disclose wherein the standard x-ray energy of the standard form image representative of the image is in the range 25-28 kVp.

Manueco Santurtun et al. discloses an x-ray generator with phase-advance voltage feedback (fig. 2) wherein the standard ("typical") x-ray energy suggested is in the range 25-28 kVp (3:3-14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made for the method of *Giger et al.* to include a standard x-ray energy in the range 25 – 28 kVp for its standard form image representative of the image as taught by *Manueco Santurtun et al.* for providing "…typical requirements for X-ray applications…", *Manueco Santurtun et al.,* 3:5-6.

It must be noted that the normalization of the subtraction image will naturally bring the values of the isolated abnormalities of the processed image back into the range of the standard x-ray energy used in the original image. In essence, the x-ray energy used to create the original image will be again seen in the normalized processed image, so motivation can also arise in using a standard x-ray energy in the original image as argued above.

Regarding **claim 10**, while *Giger et al.* discloses the method of claim 1, *Giger et al.* does not disclose wherein the standard exposure is in the range 20 – 200 milli-Ampere-seconds.

Manueco Santurtun et al. discloses an x-ray generator with phase-advance voltage feedback (fig. 2) wherein the standard ("typical") exposure suggested is in the range 20 – 200 milli-Ampere-seconds (3:3-14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made for the method of *Giger et al.* to include a standard exposure in the range 20 – 200 milli-Ampere-seconds for its standard form image representative of the image as taught by *Manueco Santurtun et al.* for providing "…typical requirements for X-ray applications…", *Manueco Santurtun et al.,* 3:5-6.

Regarding **claim 26**, claim 9 recites identical features as in claim 26. Thus, references/arguments equivalent to those presented above for claim 9 is equally applicable to claim 26.

Regarding **claim 27**, claim 10 recites identical features as in claim 27. Thus, references/arguments equivalent to those presented above for claim 10 is equally applicable to claim 27.

Giger et al. in view Saito et al.

[11] Claims 22-23, and **33** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination between *Giger et al.* in view of U.S. Patent No. 5,954,650 (issued Sep. 21, 1999, *hereinafter* "Saito et al.").

Regarding **claim 22**, while *Giger et al.* discloses a method for processing mammographic images (1:8-19) comprising the steps of:

processing a plurality of digital or digitized formed by the same mammography system to remove effects of the same mammography system and fat content in the breast being imaged, thereby forming a first processed images (refer to references/arguments cited in the first processing step of claim 1); and

converting each first processed image into a original-form x-ray mammogram having a first standard form x-ray voltage parameter and a first standard form exposure parameter (refer to references/arguments cited in the second processing step of claim 1); and

storing the standard-form x-ray mammograms (refer to references/arguments cited in claim 1)

whereby visual comparison of x-ray mammograms taken by the same x-ray mammography system is facilitated by comparing standard-form x-ray mammograms derived from mammograms taken by the same x-ray mammography system (refer to

references/arguments cited in claim 1 in the third processing step), *Giger et al.* does not teach all of the method steps performed by different x-ray mammography systems.

Saito et al. discloses a medical image processing apparatus (fig. 1) whereby visual comparison of images (fig. 1, item 1) taken by different imaging systems (fig. 1, x-ray CT image, MRI image, and fusion image) is facilitated by comparing images derived from images taken by the different images systems (1:6-14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made for all the method-steps in the method of *Giger et al.* to be performed by different x-ray mammography systems as taught by *Saito et al.* "...to provide a strongly desired medical image processing apparatus where images of the same position with the same size, which have been imaged by modalities using different imaging methods, are superimposed on and composed with each other and are displayed so as to be able to be compared with each other realistically and visually.", *Saito et al.*, 1:62-67.

Regarding **claim 23**, claim 2 recites identical features as in claim 23. Thus, references/arguments equivalent to those presented above for claim 2 is equally applicable to claim 23.

Regarding **claim 33**, while *Giger et al.* discloses a method for processing mammographic images (1:8-19) comprising the steps of:

processing a plurality of digital or digitized formed by a first x-ray mammography system to remove effects of the first mammography system and fat content in the breast being imaged, thereby forming a first processed images (refer to references/arguments cited in the first processing step of claim 1); and

processing the digital or digitized mammogram of a breast formed by a second x-ray mammography system to remove effects of the second mammography system and fat content in the breast being image, thereby forming a second processed image (refer to references/arguments cited in the first processing step of claim 1 wherein the first and second x-ray mammography systems are the same system);

converting each first processed image into a original-form x-ray mammogram having a first original x-ray voltage parameter and a first standard form exposure parameter (refer to references/arguments cited in the second processing step of claim 1); and

storing the standard-form x-ray mammograms (refer to references/arguments cited in claim 1)

whereby visual comparison of x-ray mammograms taken by the same x-ray mammography system is facilitated by comparing standard-form x-ray mammograms derived from mammograms taken by the same x-ray mammography system (refer to references/arguments cited in claim 1 in the third processing step), *Giger et al.* does not teach all of the method steps performed by different x-ray mammography systems.

Saito et al. discloses a medical image processing apparatus (fig. 1) whereby visual comparison of images (fig. 1, item 1) taken by different imaging systems (fig. 1, x-ray CT image, MRI image, and fusion image) is facilitated by comparing images derived from images taken by the different images systems (1:6-14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made for all the method-steps in the method of *Giger et al.* to be performed by different x-ray mammography systems (and hence the first and second x-ray mammography system being different) as taught by *Saito et al.* "…to provide a strongly desired medical image processing apparatus where images of the same position with the same size, which have been imaged by modalities using different imaging methods, are superimposed on and composed with each other and are displayed so as to be able to be compared with each other realistically and visually.", *Saito et al.*, 1:62-67.

Giger et al. in view of Saito et al. and Johns et al.

[12] **Claim 25** is rejected under 35 U.S.C. 103(a) as being unpatentable over *Giger et al.* in view of *Saito et al.*, and *Johns et al.*

Regarding **claim 25**, claim 7 recites identical features as in claim 25. Thus, references/arguments equivalent to those presented above for claim 7 is equally applicable to claim 25.

Giger et al. in view of Saito et al., and Manueco Santurtun et al.

[13] **Claims 26-27** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Giger et al.* in view of *Saito et al.* and *Manueco Santurtun et al.*

Regarding **claim 26**, claim 9 recites identical features as in claim 26. Thus, references/arguments equivalent to those presented above for claim 9 is equally applicable to claim 26.

Regarding **claim 27**, claim 10 recites identical features as in claim 27. Thus, references/arguments equivalent to those presented above for claim 10 is equally applicable to claim 27.

Johns et al. in view of Giger et al and Saito et al.

[14] Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable *Johns et al.* in view of *Giger et al* and *Saito et al.*

Regarding **claim 28**, while *Johns et al.* discloses a method for processing mammographic images (Section 2. Methods, page 676) comprising the step of:

forming in a first mammography system a digital or digitized mammogram of a breast along with images of first and second reference materials having thicknesses that range from 0 to the thickness of the breast (Fig. 6; Section 3.4, page 689, second paragraph), one reference material having an attenuation constant that is approximately the same as that of fat (Section I. Introduction, page 676, third paragraph) and the other having an attenuation constant that is approximately the same as that of glandular tissue (Section I. Introduction, page 676, third paragraph), *Johns et al.* does not teach the steps of:

(i) using exposure information in images of the first and second reference materials to process the digital or digitized mammogram system to remove substantially all effects related to the physical characteristics of the first mammography system and its operating parameters and the effect of fat content in the breast being imaged, thereby forming a first processed image;

(ii) converting the first processed image into a standard-form mammogram having pixel values that would have been obtained by a standard-form mammography system having a first standard x-ray voltage parameter and a first standard exposure parameter; and

(iii) storing said standard-form mammogram whereby

(iv) visual comparison of mammograms taken by different mammography systems is facilitated by comparing standard-form mammograms derived from mammograms taken by the different mammography systems.

Giger et al discloses an automated method and system for computerized detection of masses and parenchymal distortions in medical images (1:8-19) that teaches

(i) using exposure information in the images to process the digital or digitized mammogram system (5:57-59) to remove substantially all effects related to the physical characteristics of the first mammography system and its operating parameters (refer to references/arguments cited in claim 4) and the effect of fat content in the breast being imaged, thereby forming a first processed image;

(ii) converting the first processed image into a standard-form mammogram having pixel values that would have been obtained by a standard-form mammography system having a first standard x-ray voltage parameter and a first standard exposure parameter (refer to references/arguments cited in claim 8); and

(iii) storing said standard-form mammogram (fig. 27, item 2706).

It would have been obvious to one of ordinary skill in the art at the time the invention was made for the method of Johns to

(i) use exposure information in the images of the first and second reference materials of *Johns et al.* to process the digital or digitized mammogram system of *Johns et al.* to remove substantially all effects related to the physical characteristics of the first mammography system and its operating parameters and the effect of fat content in the breast being imaged, thereby forming a first processed image;

(ii) convert the first processed image into a standard-form mammogram having pixel values that would have been obtained by a standard-form mammography system having a first standard x-ray voltage parameter and a first standard exposure parameter; and

(iii) store said standard-form mammogram as taught by *Giger et al* "...to provide a method and system for detecting, classifying, and displaying lesions such as masses and tissue distortions in medical images such as images of the breast.", *Giger et al*, 1:62-65.

The above method of the combination of *Johns et al.* in view of *Giger et al* does not teach whereby visual comparison of mammograms taken by different mammography systems is facilitated by comparing standard-form mammograms derived from mammograms taken by the different mammography systems.

Saito et al. discloses a medical image processing apparatus (fig. 1) whereby visual comparison of images (fig. 1, item 1) taken by different imaging systems (fig. 1, x-ray CT image, MRI image, and fusion image) is facilitated by comparing images derived from images taken by the different images systems (1:6-14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made for the standard-form mammograms in the method of the combination between *Johns et al.* in view of *Giger et al* to facilitate visual comparison of images taken by different imaging systems by comparing images derived from images taken by the different images systems as taught by *Saito et al.* "…to provide a strongly desired medical image processing apparatus where images of the same position with the same size, which have been imaged by modalities using different imaging methods, are superimposed on and composed with each other and are displayed so as to be able to be compared with each other realistically and visually.", *Saito et al.*, 1:62-67.

Regarding **claim 29**, while the combination *Johns et al.* in view of *Giger et al* and *Saito et al.* to disclose the method of 28, the combination does not teach wherein the processing removes distinguishing effects of both of the following operating parameters of the mammography system: x-ray energy and exposure.

Giger et al discloses an automated method and system for computerized detection of masses and parenchymal distortions in medical images (1:8-19) that teaches wherein the processing removes distinguishing effects of both of the following operating parameters of the mammography system: x-ray energy; exposure (refer to references/arguments cited in claim 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made for the combination of *Johns et al.* in view of *Giger et al* and *Saito* to include wherein the processing removes distinguishing effects of both of the following operating parameters of the mammography system: x-ray energy and exposure as taught by *Giger et al* so that "..the number of false positives due to fat will be reduced.", *Giger et al*, 5:39-41.

Johns et al. in view of Giger et al., Saito et al., and Manueco Santurtun et al.

[15] **Claims 31-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Johns et al.* in view of *Giger et al.*, *Saito et al.*, and *Manueco Santurtun et al.*

Regarding **claim 31**, claim 9 recites identical features as in claim 31. Thus, references/arguments equivalent to those presented above for claim 9 is equally applicable to claim 31.

Regarding **claim 32**, claim 10 recites identical features as in claim 32. Thus, references/arguments equivalent to those presented above for claim 10 is equally applicable to claim 32.

Conclusion

[16] Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID P. RASHID whose telephone number is (571)270-1578. The examiner can normally be reached Monday - Friday 7:30 - 17:00 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vikkram Bali can be reached on (571) 272-74155. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/David P. Rashid/
Examiner, Art Unit 2624

David P Rashid
Examiner
Art Unit 26244

/Vikkram Bali/
Supervisory Patent Examiner, Art Unit 2624